RPS note: to get the 1.03 g/ml density, you'd make up a big batch of base. Then you'd add 400 mg of ibuprofen and qs to 5 ml (yes ml) with the base. Then you can weigh the 5 ml of powder (containing both ibuprofen+base). You would then have a weight for the 5 ml of powder, and can calculate the density.

Formulation Record

Name of Formulation: Ibuprofen Effervescent Powder
Strength: 400 mg/tsp
Dosage Form: Effervescent Powder
Route of Administration: Oral

Date of Last Review or Revision: 01/22/07
Person Completing Last Review or Revision: Robert Shrewsbury

Formula:

Ingredient	Quantity	Physical Description	Solubility	Therapeutic Activity
Ibuprofen	400 mg/tsp	white powder	soluble in water; soluble in most organic solvents	anti-inflammatory
Sodium bicarbonate	52.4%	white powder	1 in 11 parts water	source of carbon dioxide
Tartaric acid	28.6%	white powder	1 in 0.75 parts water	acidulant; flavor enhancer
Citric acid, monohydrate	19.0%	white granules	1 in less than 1 part water	acidulant

Additional Information:

- From a previous compound of this formulation, the bulk powder density was found to be 1.03 g/ml.

Example Calculations:

Equipment Required:

- prescription balance
- sieve, 40 mesh, 5"
- mortar and pestle

Method of Preparation:

1. Accurately weigh the powders.
2. Combine the powders using geometric dilution.
3. Sieve through a 40 mesh, 5" sieve.
4. Triturate the sieved powder.
5. Package in airtight container.

Description of Finished Product:

White to off-white powder mixture; extremely hygroscopic.

Quality Control Procedures:

Put 50 ml of Purified Water in a 100 ml beaker. Add 1 teaspoonful of the powder mixture all at once. The resulting "fizz" should fill or slightly overflow the beaker.

Packaging Container:

Package in air tight, glass jar.

Storage Requirements:

Can be stored at refrigerator or room temperature. Airtight container must be kept tightly closed.

Beyond-Use Date Assignment:

USP Guidelines:

Nonaqueous liquids and solid formulations*:*

If the source of the ingredient(s) is a manufactured drug product, the beyond-use date is not later than 25% of the time remaining until the original product's expiration date, or 6 months, whichever is earlier. If the source of the ingredient(s) is a USP or NF substance, the beyond-use date is not later than 6 months.

Assign 6 months.

Label Information:

Dissolve in water before taking

Source of Recipe:

Pharmaceutical Laboratory Web Site, http://pharmlabs.unc.edu

Literature Information:

Handbook of Pharmaceutical Excipients, 3rd edition, APhA Publications, © 2000.